Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application.

Listing of Claims:

1. (Previously presented) A propellant-free composition consisting of (A) a polypeptide, and (B) one or more surfactant compounds which (i) have a consistency that permits them to be processed into primary particles having a diameter less than 10 microns, and (ii) enhance the systemic absorption of said polypeptide in the lower respiratory tract of a patient, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device, wherein at least 50% of the total mass of (A) and (B) consists of primary particles having a diameter less than 10 microns or equal to about 10 microns, and wherein each of the one or more surfactant compounds is selected from the group consisting of a salt of a fatty acid, bile salt, single-chain phospholipid, double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length, alkyl glycoside, cyclodextrin or derivative thereof, salt of a glycyrrhizine acid, salt of a saponin glycoside, salt of an acyl carnitine, and sodium salicylate.

2. (Cancelled)

3. (Previously presented) The composition of claim 1, wherein said polypeptide is a polypeptide hormone.

4. (Previously presented) The composition of claim 3, wherein said hormone is vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), somatostatin, gonadotropin agonist, human atrial

natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

5. (Previously presented) The composition of claim 1, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade, that exerts its pharmacological effect systemically.

6. (Previously presented) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 30 kD.

7. (Previously presented) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 25 kD.

8. (Previously presented) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 20 kD.

9. (Previously presented) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 15 kD.

10. (Previously presented) The composition of claim 1, wherein said polypeptide has a molecular weight of less than 10 kD.

11. (Cancelled)

12. (Previously presented) The composition of claim 1, wherein at least one of said one or more surfactant compounds is a bile salt, an alkyl glycoside, a cyclodextrin or derivative thereof, a single-chain phospholipid, or a double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length.

13. (Previously presented) The composition of claim 1, wherein at least one of said one or more surfactant compounds is a salt of a fatty acid.

14. (Previously presented) The composition of claim 13, wherein said fatty acid has 10-14 carbon atoms.

15. (Previously presented) The composition of claim 14, wherein said fatty acid is capric acid.

16. (Previously presented) The composition of claim 1, wherein at least one of said one or more surfactant compounds is sodium caprate.

17. - 20. (Cancelled)

21. (Previously presented) A method for systemic administration of a biologically active polypeptide to a patient, comprising
providing the composition of claim 1; and

causing said patient to inhale said composition from a dry powder inhaler device for a time and under conditions effective for the polypeptide to be absorbed through epithelial cells of the lower respiratory tract.

22. (Previously presented) The method of claim 21, wherein said dry powder is provided in said dry powder inhaler device in the form of agglomerates of said particles, said agglomerates being substantially deagglomerated prior to entering the respiratory tract of said patient.

23. - 25. (Cancelled)

26. (Previously presented) The method of claim 21 wherein the polypeptide is a polypeptide hormone.

27. (Previously presented) The method of claim 26, wherein said hormone is vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), somatostatin, gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

28. (Cancelled)

29. (Previously presented) The method of claim 21 wherein the surfactant compound is a salt of a fatty acid.

30. (Previously presented) The method of claim 29 wherein the surfactant compound is sodium caprate.

31. (Previously presented) The composition of claim 1, wherein at least one of said one or more surfactant compounds is a bile salt.

32. (Previously presented) The composition of claim 31, wherein said bile salt is sodium taurocholate.

33. - 49. (Cancelled)

50. (Previously presented) The method of claim 21, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade.

51. (Previously presented) The method of claim 21, wherein said polypeptide has a molecular weight of less than 30 kD.

52. (Previously presented) The method of claim 21, wherein said polypeptide has a molecular weight of less than 25 kD.

53. (Previously presented) The method of claim 21, wherein said polypeptide has a molecular weight of less than 20 kD.

54. (Previously presented) The method of claim 21, wherein said polypeptide has a molecular weight of less than 15 kD.

55. (Previously presented) The method of claim 21, wherein said polypeptide has a molecular weight of less than 10 kD.

56. (Previously presented) The method of claim 21, wherein said surfactant compound is an alkyl glycoside, a cyclodextrin or derivative thereof, a single chain phospholipid, or a double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length.

57. (Previously presented) The method of claim 29, wherein said fatty acid has 10-14 carbon atoms.

58. (Previously presented) The method of claim 29, wherein said fatty acid is capric acid.

59. (Previously presented) The method of claim 21, wherein said surfactant compound is a bile salt.

60. (Previously presented) The method of claim 59, wherein said bile salt is sodium taurocholate.

61. - 77. (Cancelled)

78. (Previously presented) A dry powder inhaler device containing the composition of claim 1.

79. (Cancelled)

80. (Previously presented) The dry powder inhaler device of claim 78, wherein said polypeptide is a polypeptide hormone.

81. (Previously presented) The dry powder inhaler device of claim 80, wherein said hormone is vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), somatostatin, gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

82. (Previously presented) The dry powder inhaler device of claim 78, wherein said polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade.

83. (Previously presented) The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 30 kD.

84. (Previously presented) The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 25 kD.

85. (Previously presented) The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 20 kD.

86. (Previously presented) The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 15 kD.

87. (Previously presented) The dry powder inhaler device of claim 78, wherein said polypeptide has a molecular weight of less than 10 kD.

88. (Cancelled)

89. (Previously presented) The dry powder inhaler device of claim 78, wherein said surfactant compound is an alkyl glycoside, a cyclodextrin or derivative thereof, or a phospholipid.

90. (Previously presented) The dry powder inhaler device of claim 78, wherein said surfactant is a salt of a fatty acid.

91. (Previously presented) The dry powder inhaler device of claim 90, wherein said fatty acid has 10-14 carbon atoms.

92. (Previously presented) The dry powder inhaler device of claim 91, wherein said fatty acid is capric acid.

93. (Previously presented) The dry powder inhaler device of claim 78, wherein said surfactant is sodium caprate.

94. (Previously presented) The dry powder inhaler device of claim 78, wherein said surfactant compound is a bile salt.

95. (Previously presented) The dry powder inhaler device of claim 94, wherein said bile salt is sodium taurocholate.

96. (Previously presented) The dry powder inhaler device of claim 78, wherein said primary particles are formed into agglomerates, said device being configured to induce the majority of said agglomerates to break down into particles having a diameter less than 10 microns or equal to about 10 microns, upon inhalation of said agglomerates from said device.

97. (Previously presented) The dry powder inhaler device of claim 78, said inhaler device being a multi dose, breath actuated, dry powder inhaler for multiple use.

98. - 100. (Cancelled)

101. (Previously presented) The composition of claim 1, wherein the primary particles are agglomerated.

102. (Previously presented) A propellant-free composition consisting of

(A) a polypeptide;

(B) a surfactant compound that (i) has a consistency that permits it to be processed into primary particles having a diameter less than 10 microns, and (ii) enhances the systemic absorption of said polypeptide in the lower respiratory tract of a patient; and,

(C) one or more additives selected from the group consisting of a mono- or disaccharide, raffinose, melezitose, sugar alcohol and polyol, said composition being in the form of a dry powder suitable for inhalation from a dry powder inhaler device and into the lower respiratory tract, wherein at least 50% of the total mass of (A) and (B) consists of primary particles having a diameter less than 10 microns or equal to about 10 microns, and wherein the surfactant compound is selected from the group consisting of a salt of a fatty acid, bile salt, single-chain phospholipid, double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length, alkyl glycoside, cyclodextrin or derivative thereof, salt of a glycyrrhizine acid, salt of a saponin glycoside, salt of an acyl carnitine, and sodium salicylate.

103. (Previously presented) The composition of claim 102, wherein the one or more additives comprise either

(a) particles having a diameter of less than 10 microns or equal to about 10 microns, such that at least 50% of the composition consists of primary particles having a diameter of less than 10 microns or equal to about 10 microns; or

(b) coarse particles having a diameter of at least 20 microns, such that an ordered mixture is formed between (i) the one or more additives, and (ii) the polypeptide of (A) and the surfactant compound of (B).

104. (Previously presented) The composition of claim 102, wherein the polypeptide is a polypeptide hormone.

105. (Previously presented) The composition of claim 104, wherein said hormone is vasopressin, desmopressin, glucagon, corticotropin (ACTH), gonadotropin (luteinizing hormone, or LHRH), calcitonin, C-peptide of insulin, parathyroid hormone (PTH), human growth hormone (hGH), growth hormone (HG), growth hormone releasing hormone (GHRH), oxytocin, corticotropin releasing hormone (CRH), somatostatin, gonadotropin agonist, human atrial natriuretic peptide (hANP), recombinant human thyroxine releasing hormone (TRHrh), follicle stimulating hormone (FSH), or prolactin.

106. (Previously presented) The composition of claim 102, wherein the polypeptide is a growth factor, interleukin, polypeptide vaccine, enzyme, endorphin, glycoprotein, lipoprotein, or polypeptide involved in the blood coagulation cascade, that exerts its pharmacological effect systemically.

107. (Previously presented) The composition of claim 102, wherein the polypeptide has a molecular weight of less than 30 kD.

108. (Previously presented) The composition of claim 102, wherein the polypeptide has a molecular weight of less than 25 kD.

109. (Previously presented) The composition of claim 102, wherein the polypeptide has a molecular weight of less than 20 kD.

110. (Previously presented) The composition of claim 102, wherein the polypeptide has a molecular weight of less than 15 kD.

111. (Previously presented) The composition of claim 102, wherein the polypeptide has a molecular weight of less than 10 kD.

112. (Previously presented) The composition of claim 102, wherein the surfactant compound is a bile salt, an alkyl glycoside, a cyclodextrin or derivative thereof, a single-chain phospholipid, or a double-chain phospholipid in which each chain of the double-chain phospholipid is eight or fewer carbon atoms in length.

113. (Previously presented) The composition of claim 102, wherein the surfactant compound is a salt of a fatty acid.

114. (Previously presented) The composition of claim 113, wherein the fatty acid has 10-14 carbon atoms.

115. (Previously presented) The composition of claim 114, wherein the fatty acid is capric acid.

116. (Previously presented) The composition of claim 102, wherein the surfactant compound is sodium caprate.

117. (Previously presented) The composition of claim 102, wherein the surfactant compound is a bile salt.

118. (Previously presented) The composition of claim 102, wherein the primary particles are agglomerated.

119. (Previously presented) The composition of claim 102, wherein the one or more additives are selected from the group consisting of lactose, glucose, raffinose, melezitose, lactitol, maltitol, trehalose, sucrose, and mannitol.